Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	MRH Tullamore
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Arden Road, Puttaghan, Tullamore, Offaly
Type of inspection:	Announced
Date of inspection:	24 October 2023
Medical Radiological Installation Service ID:	OSV-0007365
Fieldwork ID:	MON-0036494

About the medical radiological installation:

Midlands Regional Hospital Tullamore (MRHT) is the largest hospital in the midlands of Ireland, providing acute care hospital services including a 24-hour emergency department. It is the receiving centre for all trauma activity. The hospital currently operates with 232 inpatient beds and day surgery operating through a day hospital with 28 day beds. There are also 4 Acute Medical Assessment Unit beds. MRHT is affiliated with the Technological University of Shannon (TUS) for nursing programmes and the University of Limerick for medical programmes. It is also one of two main teaching Hospitals of Trinity College Dublin - specialising in the training and professional development of staff in areas such as nursing, health and social care professionals, emergency medicine and surgery. Approximately 86,161 examinations involving the use of ionising radiation per annum are performed.

The Radiology Department provides diagnostic imaging services to inpatients, emergency department, outpatients and patients referred from primary care in the counties of Laois, Offaly, Longford and Westmeath and the surrounding area. The Radiology service is provided utilising the following imaging modalities: Main Radiology Department: 4 x digital general X-ray Room, 1 x Fluoroscopy Room, 1 x OPG, 2 x computed tomography (CT) scanner, 1 x MRI scanner and 4 x Ultrasound scanner. Outside the Radiology Department: 5 x digital mobile X-ray units and 3 x C-Arms (Theatre). Routine radiology services are provided from 9am to 5pm, Monday to Friday. There is full out-of-hours on-call cover for emergency department and inpatient x-ray. Radiation protection and medical physics services are provided by staff from the Department of Medical Physics and Bioengineering at St. James's Hospital. There is full time on-site presence of Medical Physics Expert in MRHT with additional visits for the purposes of QA and equipment commissioning.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 24 October 2023	09:30hrs to 15:30hrs	Noelle Neville	Lead
Tuesday 24 October 2023	09:30hrs to 15:30hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

An inspection of Midlands Regional Hospital Tullamore was carried out on 24 October 2023 by inspectors to assess compliance with the regulations at the facility. As part of this inspection, inspectors visited the general X-ray and computed tomography (CT) units, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking, the Health Service Executive (HSE), demonstrated compliance during this inspection with Regulations 4, 5, 6, 10, 11, 14, 16, 17, 19, 20 and 21, substantial compliance with Regulation 8 and were not compliant with Regulation 13.

Inspectors noted that there was a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation at Midlands Regional Hospital Tullamore. Inspectors noted involvement in, and oversight of, radiation protection by the hospital's medical physics expert (MPE) across a range of responsibilities. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Midland Regional Hospital Tullamore and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

A document titled *Receipt of Referrals and Justification/Approval of Medical Exposures*, the most recent version of which was published in March 2023, was in place at Midlands Regional Hospital Tullamore. This document outlined who was entitled to make a referral for a medical radiological exposure at the hospital. Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff

that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Midlands Regional Hospital Tullamore.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms (organisational charts that show the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Midlands Regional Hospital Tullamore. Inspectors noted involvement in, and oversight of, radiation protection by the hospital's medical physics expert (MPE) across a range of responsibilities. In addition, inspectors noted that responsibilities were clearly allocated to referrers and practitioners with regard to medical radiological exposures taking place at the hospital.

Midlands Regional Hospital Tullamore was part of a joint radiation safety committee (RSC) with another midlands hospital and this committee met twice a year. Inspectors reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership including a radiologist, representative of the hospital manager, radiographic services manager, radiation safety officers, medical physics experts and representatives from nuclear medicine, theatre and speech and language therapy. The committee was incorporated into local governance structures, reporting to the hospital manager. Inspectors were informed that there was also a radiation protection unit (RPU) in place at the hospital. This unit was responsible for operational issues relating to radiation protection and its membership included a radiation protection adviser, medical physics expert, radiographic services manager and radiation safety officer.

Overall, inspectors were satisfied that the undertaking, the Health Service Executive, had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical

aspects of medical radiological procedures were only carried out at Midlands Regional Hospital Tullamore by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. A number of clinical audits reviewing the optimisation of different procedures were also reviewed which included input from MPEs, radiologists and radiographers. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Midlands Regional Hospital Tullamore.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Midlands Regional Hospital Tullamore and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted MPE involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Midlands Regional Hospital Tullamore. The MPE was a member of the hospital's radiation safety committee and radiation protection unit. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection. Inspectors noted that the MPE liaised with the hospital's radiation protection adviser and so met the requirements of Regulation 20(3).

Judgment: Compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices

From documentation reviewed and discussion with staff, inspectors were satisfied that the level of MPE involvement at Midlands Regional Hospital Tullamore was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the general X-ray and CT units at the hospital, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Midlands Regional Hospital Tullamore. While Regulations 11, 14, 16 and 17 were compliant, inspectors noted that there was further work required to bring Regulations 8 and 13 into compliance.

In relation to Regulation 8, inspectors noted that justification in advance as required by Regulation 8(8) was not recorded as required by Regulation 8(15) for all medical exposures. The Health Service Executive, as the undertaking for this hospital, should ensure that all individual medical exposures carried out on its behalf are justified in advance and that records evidencing this are retained to ensure compliance with Regulations 8(8) and 8(15).

In relation to Regulation 13(2), inspectors found that while information relating to the patient exposure formed part of the report for nuclear medicine, it was not available for all CT, general X-ray and theatre reports reviewed. The undertaking, the Health Service Executive, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Overall, noting that improvements were required to bring Regulations 8 and 13 into compliance, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users and displayed on posters throughout the facility.

A document titled *Receipt of Referrals and Justification/Approval of Medical*

Exposures, the most recent version of which was published in March 2023 was in place at Midlands Regional Hospital Tullamore. This document outlined the justification procedure in place at the hospital for each modality and the method of recording same. Inspectors reviewed a sample of records for CT, general X-ray, nuclear medicine and theatre and noted that while justification in advance was recorded for all CT and general X-ray exams reviewed, there were some gaps in the records reviewed for nuclear medicine and theatre. The undertaking, the Health Service Executive, should ensure that all individual medical exposures carried out on its behalf are justified in advance and that records evidencing same are retained to ensure compliance with Regulations 8(8) and 8(15).

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

A document titled *Guidelines for establishing and reviewing LDRLs*, the most recent version of which was published in January 2023, was in place at Midlands Regional Hospital Tullamore. This document set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. It stated that local DRLs are established biennially and DRL reviews are conducted annually with special attention given to higher dose modalities. Inspectors found that local DRLs had been established, regularly reviewed and used, having regard to national DRLs at the hospital as required by Regulation 11(5). Inspectors reviewed a document titled *Review of Patient Dose and Diagnostic Reference Levels* dated October 2023. This report included an annual review of typical doses received by service users at the hospital and a proposed local DRL for each commonly performed exam. The report also included corrective actions for a small number of exams which consistently exceeded the national DRL as required by Regulation 11(6). These corrective actions included protocol review and further dose audits.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Midlands Regional Hospital Tullamore for standard radiological procedures as required by Regulation 13(1). Referral guidelines were adopted at the hospital and were available to staff and referrers as required by Regulation 13(3). In addition, inspectors noted a range of clinical audits which were ongoing and complete at Midlands Regional Hospital Tullamore. These audits included pregnancy status documentation, triple identification documentation and

recording justification.

Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. Inspectors reviewed a sample of reports for CT, general X-ray, nuclear medicine and theatre medical radiological exposures and found that while information relating to the patient exposure formed part of the report for nuclear medicine, it was not available for CT, general X-ray and theatre reports reviewed. Inspectors were shown a communication from the undertaking, the Health Service Executive, which was issued to hospital group chief executive officers on 13 September 2023 and included a number of measures available to staff to facilitate compliance with this regulation. Staff confirmed to inspectors that the measures outlined by the HSE had not been fully implemented for all modalities at the hospital. However, inspectors were informed that following the receipt of a second communication from the HSE's National Integrated Medical Imaging System (NIMIS) team on 16 October 2023, the hospital were in a position to implement one of the suggested measures and this would take place imminently. The undertaking, the Health Service Executive, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Midlands Regional Hospital Tullamore as required by Regulation 14(1). Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The *Radiation Safety Policy* in place at the hospital set out the quality assurance tests required and the frequency of tests for each modality in use at the hospital. Inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

There was a document in place at Midlands Regional Hospital Tullamore titled *Policy for the protection of the unborn child arising from ionising radiation received during*

medical diagnostic or therapeutic procedures, the most recent version of which was published in January 2022. This policy included information on the pregnancy procedures in place at the hospital including the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures was implemented at Midlands Regional Hospital Tullamore. The incident management process in place at the hospital was outlined in a document titled *Radiation Incident Reporting*, the most recent version of which was published in February 2023. This protocol included information on the requirement to notify HIQA of certain reportable incidents. Inspectors noted that three incidents had been reported to HIQA within the required timelines since the commencement of the regulations in 2019. In addition, inspectors were provided with a summary report containing trending and analysis of radiation incidents and near misses for 2022 and an interim report for 2023. Inspectors were informed that these reports are discussed at the radiation safety committee.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for MRH Tullamore OSV-0007365

Inspection ID: MON-0036494

Date of inspection: 24/10/2023

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: • Nuclear Medicine – following discussion at the recent RSC meeting (10/11/2023) approval was sought for the Nuclear Medicine CSR to justify nuclear medicine bone scan requests via the vetting module on RIS. This change will be put in place by 8/12/2023 and the policy 'RADGEN 005 – Receipt of Referrals and Justification/Approval of Medical Exposures' amended to reflect changes by the 18/12/23. This change to workflow will ensure 'justification in advance' will be carried out and documented for all nuclear medicine examinations. • Theatre - all theatre radiographers were reminded to record justification of the medical exposure in the comments section of the patients file on RIS (via group communication on 8/12/23). These records will be audited monthly until 100% compliance is reached. Audit results will be published and communicated to all MRHT radiographers.	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: On the 16/10/23 a national solution was put in place to populate the dose in the report. This is available to use through the report dictation software. This solution has been implemented in the Radiology department in the MRHT as of 11/12/23. The following text is appended to every radiological report: RADIATION DOSE INFORMATION: If this patient had a medical exposure to ionising radiation you will find information	

relating to the exposure at www.hse.ie/radiationdoses.
The patient/doctor can also contact the department where the procedure was carried out for the specific radiation dose associated with the procedure.
Ionising radiation is not used in Ultrasound, MRI, Respiratory Procedures (PFT/PSG) or Cardiac Investigation Procedures (CI).

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	18/12/2023
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	18/12/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report	Not Compliant	Red	02/01/2024

	of the medical radiological procedure.			